November 2, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 00D-1274
Request for Comments
Guidance Document Relating to Agency Interpretation of Section 216 of FDAMA

To whom it may concern:

I am respectfully submitting comments regarding the Food and Drug Administration's (FDA's) draft guidance document relating to the Agency's interpretation of Section 216 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Rather than detail the numerous discrepancies and contradictions that exist within the draft document, I will only highlight the most egregious aspects of FDA's approach to this statutory provision.

Let me begin by pointing out that from a legal standpoint, the FDA's interpretation is simply contrary to law. While the FDA has cleverly presented one interpretation of the legislative history of the Federal Food, Drug, and Cosmetic Act to support its convoluted position, anyone taking the time and expending the effort to review the references that are provided in the guidance document can easily draw opposite conclusions. I suspect that one or two individuals within FDA decided the Agency's course of action and then asked the attorneys to find the necessary words of support. I am convinced that if there had been broad participation by regulators knowledgeable of the medical device industry, guided by the sound legal advice of the FDA's Office of General Counsel, the outcome of the deliberations would have been quite different.

Possibly the most disappointing and troubling aspects of FDA's approach to interpreting and implementing Section 216 of FDAMA is evident from the recent history. Rather than resolve the controversy that arose shortly after enactment of FDAMA that related to this provision's retroactivity, the FDA chose to secretively draw legal conclusions and apply them to at least one regulatory decision without public disclosure. It appears that FDA determined shortly after the enactment of FDAMA that it was appropriate (or in someone's best interest) to retroactively apply Section 216 to make data in approved PMAs available to support the reclassification of extracorporeal shock was lithotriptors. I find no evidence that the FDA disclosed the fact that it was using data in approved PMAs in support of the reclassification action. Did the petitioner know? Did the advisory panel know? Does it not appear underhanded that the FDA chose to use PMA data under Section 216 that it now professes not to have impacted the final decision? I believe that I know the answers to these questions, and if I am correct, the FDA has some significant integrity problems. Clearly, the FDA has difficulty upholding the standards that it expects the regulated industry to meet.

Lastly, it appears that authors of the guidance document entitled "Evidence Models for the Least Burdensome Means to Market" (released in September 1999) were also the authors of this guidance document. Evidence of the same disjointed cognitive processes pervades both documents. It is my hope that the FDA will not only abandon its current approach to the implementation of Section 216, but also give the individuals responsible for its creation assignments where they can do no further damage.

Thank your for the opportunity to comment on this topic.

Steven Rohr

00D-1274

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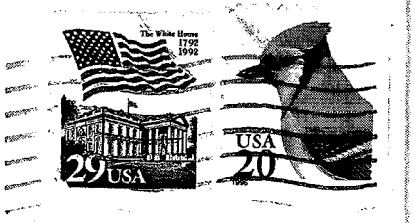

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